

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/271,024	03/17/1999	ASGEIR SAEBO	CONLINCO-036	3480
	7590 03/10/2004		EXAMINER	
MEDLEN & CARROLL, LLP 101 HOWARD STREET			WANG, SHENGJUN	
SUITE 350 SAN FRANCISCO, CA 94105		ART UNIT	PAPER NUMBER	
		1617		

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.usplo.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 20040305

Application Number: 09/271,024 Filing Date: March 17, 1999 Appellant(s): SAEBO ET AL.

MAILED

MAR 1 0 2004 GROUP

J. Mitchell Jones For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 25, 2003.

Application/Control Number: 09/271,024 Page 2

Art Unit: 1617

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existance of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 5-8 and 13-17 stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

Application/Control Number: 09/271,024 Page 3

Art Unit: 1617

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

US Patent 5,017,614

Pariza et al.

May 21, 1991

US Patent 5,885,594

Nilsen et al.

March 23, 1999

WO 97/18320

Cain et al,

May 22, 1997

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 5-8 are rejected under 35 U.S.C. 102 (a)

- 2. Claims 13-17 are rejected under 35 U.S.C. 103(a)
- 3. Claims 5-8 and 13-17 are rejected under 35 U.S.C. 103(a)

These rejections are fully set forth in prior office action, paper No. 26, mailed March 26, 2003

(11) Response to Argument

1. Claims 5-8 are anticipated by Cain et al. Cain et al. teaches an acylglycerol composition comprising mono- di- and tri-glyceride wherein the fatty acid are c9, t11 CLA (Conjugated Linoleic Acid) or t10, c12 CLA, wherein the total CLA in the composition is about 63.8%, of which 48.9% was the cis 9, trans 11 isomer and 51.1 % was the trans 10, cis 12 isomer. No other CLA isomers are indicated, or suggested to be present in the composition. Specifically, Cain teaches an acylglycerol composition comprising mono- di- and tri-glyceride wherein the fatty acids are c9, t11 CLA or t10, c12 CLA, no other isomer was employed for the esterification forming the acylglycerol composition. See, example 6-10 at page 16-22. Further, Cain et al. have characterized all the fatty acid through gas chromatography and have identified the CLA. For

Art Unit: 1617

example, in example 6, it state "The fatty acid composition of the product, as determined by FAME GC, contained 63.8% CLA, of which 48.9% was the cis 9, trans 11 isomer and 51.1% was the trans 10, cis 12 isomer." See page 16, lines 17-21. It is suggest that the rest of the fatty acids are not CLA, and the CLA is composed entirely of cis 9, trans 11 isomer and trans 10, cis 12 isomer. (48.9% + 51.1% = 100%).

Appellants allege that Cain et al composition in fact comprises significant amount of other isomers, based on appellants' own experimental data and assumption that "method for the analysis of CLA were rather crude and Cain may have simply chosen not to include non-active isomers when reporting their results." (Declaration of Sæbo, filed December 19, 2002, paragraph 5). This was found not convincing. Note the fact that Cain et al. acknowledges other CLA isomers, and gave the data to 0.1% accuracy. "Conjugated Linoleic Acid", by its plain definition, includes all 8 isomers acknowledged by Cain. Applicants improperly interpretated Cain's teaching by limit CLA to c9, t11 CLA and t10, c12 isomers. Cain states state "The fatty acid composition of the product, as determined by FAME GC, contained 63.8% CLA, of which 48.9% was the cis 9, trans 11 isomer and 51.1% was the trans 10, cis 12 isomer." See page 16, lines 17-21. Note CLA is conjugated linoleic acids, including those identified as impurities herein. (both 8,10; 11,13; or trans, trans isomers are conjugated linoleic acids). Cain et al do not expressly teach what the remain 36.2 percent of the fatty composition are. However, nowhere in Cain states that "conjugated linoleic acid" are exclusively for c9, t11; and t10, c12 isomers. Any new definition of "CLA" would be improper.

In response to appellant' arguments that Mr. Saebo's experiments show that fatty composition obtained by Cain would comprise significant amount of 8,10; 11, 13 and other

Art Unit: 1617

isomers, note Applicant generated data, proffered to obviate prior art teachings, lacks the probative force accorded data generated by independent, disinterested parties. It is well settled patent law "that it is not a difficult matter to carry out a process in such a fashion that it will not be successful and, therefore, the failures of experimenters who have no interest in succeeding should not be accorded great weight" In re Michalek, 74 USPQ 108, at 109 citing Bullard Company et al v. Coe, 147 F.2d. 568, 64 USPQ 359. Further, no other references show that the isomers herein identified would be produced in significant amounts under Cain's conditions, such as those disclosed in example 6. Considering all the facts on the record, there is no convincing evidence showing that Cain's composition has the amount of the particular isomers herein claimed.

- 2. With respect to appellants' remarks about "inherency," note the issue is whether appellants may impose a limitation to a prior art, where the prior art does not teach, or suggest such limitation. As discussed above, appellants may not do that.
- 3. Appellants' assertion that the decision of <u>In re Michalek</u> is in conflict with current case law and PTO practice is incorrect. In re Michalek states evidence produced by applicants "should not be accorded *great weight*." (Emphasis added). Current case law and PTO practice do not provide any thing contrary. In fact, <u>In re Michalek</u> is recited in the current MPEP (see MPEP 716.07). Note "avoid giving evidence *no weight*" is not "be accorded *great weight*." Appellants generated data conflict with prior art teaching. Considering all the facts, the prior art's teaching prevail.

Art Unit: 1617

Claims 13-17 are obvious over Cain et al. For reasons discussed above, and further Cain teaches the composition may be used in various food products including ice cream, soup, and bakery products. See, particularly, examples 12-17 at page 24-35 and the claims.

Claims 5-8 and 13-17 are obvious over Nilsen et al. (US 5,885,594) in view of Cain et al. (WO 97/18320, IDS), further in view of Pariza et al. (U.S. Patent 5,017,614)

Nilsen et al teach a composition comprising 90-100 % of an acylglycerol compound wherein the fatty acid radical is a conjugated polyunsaturated fatty acid. See, particularly, column 3, lines 5-15. The preferred conjugated polyunsaturated fatty acid is conjugated linoleic acid which is defined as c9, t11-octadecadienoic acid and/or c10, t12-octadecadienoic acid. See, particularly, column 3, lines 14-15 and column 4, lines 4-6. Nilsen et al. further teaches food product comprising the said composition. See, particularly, column 12, lines 30-67, column 13, lines 1-67 and column 14, lines 1-9.

Nilsen et al. do not teach expressly the employment of the combination of c9, t11-octadecadienoic acid and/or t10, c12-octadecadienoic acid in the acylglycerol, or the specific amounts of each of the two isomers, i.e., c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid, or the employment of the composition in animal feed.

However, Cain et al. teach that both c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid are considered the active isomers of CLA, and are known to be beneficial for animal health, See, particularly, page 1, lines 8-25. Cain further teaches a method of making both c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid. See, particularly the examples.

Art Unit: 1617

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make the composition of Nilsen et al. with acylglycerol compounds wherein the fatty acid moiety is a mixture of about equal amounts of c9, t11-octadecadienoic acid and t10, c12-octadecadienoic acid and employ the composition food. Note that Nielsen et al do not use the other isomers of conjugated linoleic acids specified herein. Therefore meet the limitation set forth in claim 5 that other isomers are present in amounts less than 1% is meet.

A person of ordinary skill in the art would have been motivated to make the composition of Nielsen et al. with acylglycerol compounds wherein the fatty acid moiety is a mixture of c9, t11-octadecadienoic acid and c10, t12-octadecadienoic acid only without employing other isomers, and employ the composition in food product because both isomers are known to be the active isomers and are useful in food products. The optimization of the ratio of the compounds is considered within the skill of artisan. Further, a composition known to be useful in food products is reasonably expected to be useful in feed products for animal. Further, Pariza is cited to show that person of ordinary skill in the art possess the skill of preparing/or isolating the pure single isomer employed herein. See, particularly, column 4, line 50, bridging column 8, lines 68, wherein, the separation, purification, and analysis of the isomers are discussed.

In response to appellant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Art Unit: 1617

4. Appellants assert that Cain et al. does not teach composition comprising less than 1% of 8,10; 11:13; trans-trans isomers. The assertion is not convincing as discussed above. Appellants do not dispute that c9, t11; t10, c12 are the two known active CLAs.

Appellants argue that "Nielsen do not teach any method at all" for making CLA. As noted above, the rejections are based on the combination of all cited references. Further, appellants' suggestion that Pariza's disclosure is not enabled is not proper. Since every patent is presumed valid (35 U.S.C. 282), and since that presumption includes the presumption of operability (Metropolitan Eng. Co. v. Coe, 78 F.2d 199,25 USPQ 216 (D.C.Cir. 1935) (MPEP 716.07). Particularly, one of ordinary skill in the art would have been expected to be able to practice the invention claimed by Nielsen, including making an acylglycerol compound wherein the Rs are conjugated linoleic acids (specifically defined as c9, t11; t10, c12 isomers), see the claims in Nielsen et al.

Appellants concedes that Paris et al. does provide purified CLA isomers, but nevertheless argue that Pariza's disclosure is for producing standard samples for HPLC, and is not in a scale suitable for making acylglycerol herein claimed. The examiner notes that there is no limitation as to the quantity of the composition in claims 5-8. Further, even Pariza does not teach expressly large scale purification, a method of large scale separation/purification would be obvious in view of Pariza's teaching. One of ordinary skill in the art would have been motivated to make purified c9, t11; t10, c12 ismoers in viw of the teachings by Nielsen et al. and Cain et al. Particularly, preparative HPLC would be obvious to one of ordinary skill in the art with similar condition. For the above reasons, it is believed that the rejections should be sustained.

Art Unit: 1617

Respectfully submitted,

Shengjun Wang Primary Examiner Art Unit 1617

> SHENGJUN WANG PRIMARY EXAMINER

March 8, 2004

Conferees

RUSSELL TRAVERS PRIMARY EXAMINER GROUP 1200

J MITCHELL JONES MEDLEN & CARROLL 220 MONTGOMERY STREET SUITE 2200 SAN FRANCISCO, CA 94104

> SPEENI PADMANABHAN SUPERVISORY PATENT EXAMINER